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SUMMARY STATEMENT

BY

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ON RECOMBINANT DNA TECHNOLOGY

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

SENATE COMMITTEE ON HUMAN RESOURCES

APRIL 6, 1977

I. INTRODUCTION

Good day, Mr. Chairman and other Committee members. It is a pleasure to have the opportunity to discuss with you Federal policies concerning recombinant DNA techniques. The focus of my remarks will be the activities of two organizations--the National Institutes of Health and the Federal Interagency Committee on Recombinant DNA Research.

As you know, recent scientific developments in genetics, particularly in the last four years, have culminated in the development of a powerful new tool for research--the ability to join together genetic materials in cell-free systems to form recombinant DNA molecules. This new technology has generated great hope and excitement and, concomitantly, some expressions of concern.

The public should expect this significant research to continue under strict conditions ensuring safety, until the potential risks are better delineated and evaluated in light of developing scientific knowledge. This was the fundamental principle that guided the National Institutes of Health and the Federal Interagency Committee in their deliberations. I would like to briefly review with you the activities of the NIH in developing guidelines to govern this research before discussing the work of the Interagency Committee.

II. DEVELOPMENT OF THE NIH GUIDELINES

The first step in the development of the Guidelines was taken by the scientific community. Scientists first expressed concern about the potential biohazards at the Gordon Research Conference on Nucleic Acids in July 1973. At their request, the National Academy of Sciences created a committee that called for a moratorium on certain types of experiments and for an international conference to consider this problem further. The committee also called on the NIH to establish an advisory committee to study containment procedures and to draft guidelines for the conduct of this research. At the International Conference on Recombinant DNA Molecules held at Asilomar, California, in February 1975, temporary guidelines were issued including a continued moratorium on some experiments but allowing others to proceed with appropriate biological and physical safeguards, pending issuance of NIH guidelines.

The NIH Recombinant DNA Molecule Program Advisory Committee, in December 1975, after several open meetings, recommended proposed guidelines for my review and decision.

To assist me in the review of the proposed guidelines, a special meeting of the NIH Advisory Committee was convened in February 1976. Members of the Committee represented not only science but such other disciplines as law, ethics, and consumer affairs. Comments received from committee members and a number of public witnesses represented a wide range of views. Meetings for information exchange were also held

with other Federal agencies, private industry, and Congressional staffs. Finally, on June 23, 1976, with the approval of the Secretary of HEW and the Assistant Secretary of Health, the NIH issued guidelines to govern the research it supports involving recombinant DNA molecules. The NIH Guidelines established strict conditions for the conduct of this research, prohibiting certain types of experiments and requiring special safety conditions for other types. The provisions were designed to afford protection--with a wide margin of safety--to workers and the environment. Two weeks later, on July 7, 1976, the NIH Guidelines--together with a document indicating the basis of my decisions on principal issues--were published in the Federal Register

Over 40,000 copies of the Guidelines have been distributed to foreign embassies, medical and scientific journals, NIH grantees and contractors, and major professional research societies.

III. NIH ACTIVITIES FOLLOWING RELEASE OF THE GUIDELINES

To facilitate implementation of the Guidelines, the NIH, in June 1976, established the Office of Recombinant DNA Activities. To document the development of the Guidelines, NIH published a document, in August 1976, containing correspondence results of relevant meetings, and my decision paper. A second volume will be published containing documents concerning the Environmental Impact Statement and HEW patent policy.

IV. THE INTERAGENCY COMMITTEE ON RECOMBINANT DNA RESEARCH

I would now like to discuss the activities of the Interagency Committee on Recombinant DNA Research. This Committee was created to address extension of the NIH Guidelines beyond the NIH, to the public and private sectors. The Committee includes representatives of Federal agencies which support recombinant DNA research or could potentially serve a regulatory role for recombinant DNA. I am the Chairman of the Committee.

The first meeting of the Committee, November 4, 1976, was devoted to a review of the development of the NIH Guidelines and a review of activities in other countries.

Recombinant DNA research is being conducted in western Europe, eastern Europe, the Soviet Union, and Japan.

In many countries, appropriate governmental or scientific bodies have reviewed the research and have agreed that it should proceed. Several of the countries, including the United Kingdom and Canada, have acted to establish guidelines to govern the conduct of this research.

The European Science Foundation, representing member nations from Western Europe and Scandinavia, has recommended to its members that they follow the guidelines of the United Kingdom. These guidelines are, in intent and substance, very similar to those of the National Institutes of Health. The NIH is currently working very closely with the United Kingdom and the European Science Foundation to ensure a commonality of

standards in carrying out this research. Thus far, there has been very close cooperation and coordination among the various international and national scientific bodies, with a view to reaching a consensus on safety practices, programs, and procedures.

At the meeting of the Committee held on November 23, 1976, the agencies discussed their activities and possible role in the implementation of the NIH Guidelines. All of the research agencies endorsed the Guidelines.

A. Subcommittee Review of Existing Legislation

In order to further explore the relevant regulatory authorities, a special Subcommittee was formed to analyze relevant statutory authorities for possible regulation of research involving recombinant DNA technology. The Subcommittee consisted of representatives of each regulatory agency assisted by attorneys from their offices of general counsel.

It was the conclusion of the Subcommittee that no single legal authority or combination of authorities currently existed that would clearly reach all research and other uses of recombinant DNA techniques.

The Subcommittee, in reaching this conclusion, reviewed the following laws that were deemed to warrant detailed consideration: the Occupational Safety and Health Act, the Toxic Substances Control Act, the Hazardous Materials Transportation Act, and section 361 of the Public Health Service Act.

The full Committee adopted the report of its Subcommittee and agreed that new legislation was required.

B. Interagency Committee Analysis of Elements for Legislation

In considering the elements for legislation, the Committee reviewed Federal, State, and local activities bearing on the regulation of recombinant DNA research. Additionally, the views of several interested parties were solicited. They included agricultural scientists, biomedical scientists, environmentalists, labor unions, and private industry.

After detailed deliberations at meetings on March 10 and 14, 1977, the Committee agreed on a set of elements for proposed legislation. The elements agreed upon and the various alternatives reviewed by the Committee were presented in an Interim Report transmitted to HEW Secretary Califano on March 15, 1977. He released the report to the public the following day.

Mr. Chairman, I would like to submit for the record the Federal Interagency Committee's "Interim Report on Suggested Elements for Legislation," along with a copy of the Secretary's press release.

With your permission, I would like to review briefly some of the major elements addressed by the Committee.

The Committee determined that the Department of Health, Education, and Welfare is the appropriate locus for the regulation of the use and production of recombinant DNA molecules.

The Committee reviewed at great length the nature and scope any legislation should have. There was general agreement that legislation should be restricted to recombinant DNA techniques. However, in

recognition of future interest in other biohazards, I have established a committee at the NIH, chaired by Dr. Richard Krause, Director, NIAID, to study and recommend, if necessary, safety standards for other NIH-supported research involving actual or potential biohazards.

Regulation of just the research aspects of recombinant DNA techniques presents a problem because of the difficulty in determining the border between research and pilot production. Therefore, the Committee recommends that regulation cover the production or use of recombinant DNA molecules. Such language would make immaterial disagreement as to whether a given activity constitutes research, pilot production, or manufacture.

The consensus of the Committee was that registration of projects involving the use or production of recombinant DNA molecules was necessary. The Committee also recommends that facilities be licensed and that the terms of the license include acceptance of responsibility for the particular activities and individuals at the facility. As embodied in the HEW bill, licensing and registration would insure that all users of recombinant DNA techniques would be known and would be adhering to the Guidelines.

There are a number of other recommendations, and I can discuss them further if you have questions. I would like to emphasize that the work of the Interagency Committee has been done in a most cooperative and helpful way, and DHEW is committed to continued cooperation and coordination with relevant Federal Departments and Agencies.

IV. CONCLUSION

In conclusion, this much is clear: the international and national scientific community is in substantial agreement that, until the potential hazards of recombinant DNA techniques are better understood, a common set of standards must everywhere exist for the use of those techniques. The question being debated now is how this is to be accomplished.

In the United States, this question has attracted far more public attention than in other countries; indeed, a number of local jurisdictions or States are engaged in action or debate.

Finally, I want to note that biomedical research is entering a new era in its relationship to society. It is passing from an extended period of relative privacy and autonomy to an engagement with new ethical, legal, and social imperatives under concerned public scrutiny. NIH has responded to these concerns by requiring the formation of review boards to oversee human experimentation, animal care, and now DNA recombinant experiments. Similar bodies may soon have to oversee other hazardous laboratory work. These responsibilities are inescapable adjustments to the rising demand for public governance of science, though this need--and, indeed, should not--go beyond what is clearly required for public safety lest we inadvertently impede successful research and hamper creativity. The progress of science will continue to depend on the initiative and insights--call it inspiration, if you like--of individual scientists.